

Pelvic floor muscle training for women with pelvic organ prolapse: the PROPEL realist evaluation

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Scientific summary

The PROPEL realist evaluation

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Scientific summary

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Background

Pelvic organ prolapse can affect up to half of the female population aged > 40 years. Surgery has been the main treatment option for most women, but many women experience an additional prolapse and around 30% of women have repeat surgery. Repair of one type of prolapse may also predispose the woman to the development of a different type of prolapse in another compartment of the vagina. Concerns remain surrounding the use of synthetic mesh in prolapse surgery, which has resulted in complications and a removal rate of up to 35%.

Given these events, there is an ever more pressing need for evidence-based non-surgical options to be made available to women. A recent definitive trial, the Pelvic Organ Prolapse Physiotherapy (POPPY) trial [Hagen S, Stark D, Glazener C, Dickson S, Barry S, Elders A, *et al.* Individualised pelvic floor muscle training in women with pelvic organ prolapse (POPPY): a multicentre randomised controlled trial. *Lancet* 2014;**383**:796–806], has shown that pelvic floor muscle training is an effective and potentially cost-effective treatment, which should be recommended as a first-line treatment for pelvic organ prolapse. The POPPY trial constitutes the largest, most rigorous, pragmatic trial of pelvic floor muscle training for prolapse, and, therefore, provides the necessary evidence to inform future practice.

Despite this evidence, provision of pelvic floor muscle training for pelvic organ prolapse continues to vary across the UK, with limited numbers of physiotherapists with specialist training in pelvic floor dysfunction/women's health. There are approximately 2600 symptomatic women for each specialist physiotherapist in the UK. If this robust evidence-based treatment is to be implemented, it will require attention to alternative modes of delivery and service organisation to meet the needs of the large numbers of women who could benefit from it. Training other relevant health-care staff, such as nurses involved in women's health (e.g. continence nurses and urogynaecology nurses), midwives, junior (grade 5) physiotherapists or other specialist physiotherapists (e.g. musculoskeletal), could be an option for increasing the necessary provision and improving access to it. However, this might also require service reorganisation, including the development of operational processes (e.g. triage), as it is likely to be a shared model in which more severe cases can be prioritised to the specialists and more straightforward cases to the newly trained staff.

Implementation research can help to understand the mechanisms at play when successful implementation of this evidence-based intervention is observed. It can also test the different modes of delivery that may be required for successful 'real-world' implementation. This requires working with local NHS sites to allow them to make decisions about how they want to implement the pelvic floor muscle training intervention to increase service provision locally, without compromising expected outcomes and quality of care for women with pelvic organ prolapse.

An observed reduction in 'further treatment' following pelvic floor muscle training was initially established in the POPPY trial, but this did not allow for lengthy follow-up of trial participants. Recent investment in Scotland in health data linkage makes it possible to follow up the original POPPY trial participants using hospital admission and hospital outpatient data sets. This type of knowledge can help inform NHS managers by predicting the longer-term benefits that they might expect if they implement a pelvic floor muscle training service.

The research questions were as follows:

1. Can pelvic floor muscle training be successfully delivered using different staff groups/skill mixes and what are the barriers to and facilitators of successful implementation of pelvic floor muscle training across different service models and settings?
2. Does the pelvic floor muscle training intervention, as implemented, improve pelvic organ prolapse symptoms in women?
3. Does the effect differ significantly when delivered by specialist physiotherapists rather than other health-care professionals?
4. What are the costs associated with the different models of delivery?
5. Are women who were included in the original POPPY intervention in Scotland less likely to receive further secondary care treatment related to their prolapse during the follow-up period than women who were in the control condition?

Aim

The first aim was to maximise the delivery of effective pelvic floor muscle training for women with prolapse, through the study of its implementation in three diverse settings using an evidence-based pelvic floor muscle training protocol. Implementation of pelvic floor muscle training in diverse settings will involve developing different service delivery models, incorporating a variety of staff skill mixes (and, potentially, numbers of sessions) to increase capacity, with the format of delivery being determined locally.

The second aim was to assess the impact of pelvic floor muscle training on longer-term treatment outcomes using linked health-care data for the majority of the original POPPY trial participants (i.e. those based in Scotland).

Methods

The study involved the following research questions.

Research question 1

A realist evaluation was carried out that used case studies of implementation of pelvic floor muscle training delivery in three different NHS settings. The realist evaluation allowed for substantial local stakeholder engagement and for local sites to make decisions on how to deliver pelvic floor muscle training (e.g. using different skills mixes and numbers of sessions). Qualitative data for the realist evaluation were collected at four time points over an 18-month intervention period to understand local contexts and decisions regarding the delivery of pelvic floor muscle training for prolapse and to monitor implementation, uptake, adherence and impact. Interviews were conducted with service managers/leads, consultants, specialists in women's health, and staff with the potential to deliver pelvic floor muscle training. Round 1 ($n = 21$) and round 2 ($n = 46$) interviews tracked local decisions on 'how to implement pelvic floor muscle training services' and elicited their 'theories of change'. Training in delivering pelvic floor muscle training was then provided to identified staff groups in each case study site and two further sites (collecting outcome data only). Round 3 ($n = 20$) interviews

focused on implementation of services ('how is it working?') and round 4 ($n = 24$) interviews reflected on the overall experience of service delivery ('did it work/what worked?'). Rounds 3 and 4 included interviews with women referred to services.

Dissemination and implementation workshops (England and Scotland) were run at the end of the study to discuss the applicability of study findings and outcomes with service managers, women's health-care professionals, general practitioners and patient and public representatives from across the country, with discussion of implications for planning of local services and identification of any further key barriers to, or facilitators of, change.

Research questions 2 and 3

A robust patient-reported outcome measures study, which used the same outcome measures as the original POPPY trial, was conducted in five NHS sites (three case study sites plus two additional sites) to observe the outcomes for women receiving the different models of care. Patient outcomes were collected at baseline and at the 6- and 12-month follow-ups. Patient demographic data (e.g. age, ethnicity, occupation and educational attainment) were also collected. The primary outcome was the Pelvic Organ Prolapse Symptom Score. The secondary outcomes were quality-of-life outcomes (measured using the EuroQol-5 Dimensions, five-level version), pelvic floor-related outcomes (prolapse severity: Pelvic Organ Prolapse Quantification System), urinary symptoms (measured using the International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form) and service-related outcomes (need for further treatment).

Research question 4

An economic evaluation was carried out to assess the associated costs and outcomes of different service delivery models for delivering pelvic floor muscle training. In addition, an economic assessment of the long-term costs associated with accessing further pelvic prolapse treatment over time was conducted for the original POPPY trial participants who were resident in Scotland.

Research question 5

Long-term follow-up of up to 11 years of the original POPPY trial participants was carried out using record linkage of hospital and outpatient data (provided by Information Services Division Scotland via the NHS electronic Data Research and Innovation Service).

Results

Research question 1

Five NHS sites were recruited to deliver pelvic floor muscle training using a range of delivery models. Site A comprised an exclusively specialist physiotherapy service model that then acted as a comparator for delivery by 'other' staff groups (nurses, physiotherapists), as developed by sites B–E. Successful implementation of pelvic floor muscle training required adequate training tailored to the differential needs of skill mix, increased awareness of pelvic floor muscle training among general practitioners and other health-care professionals, well-co-ordinated and flexible referral systems, wider (multidisciplinary) team support/buy-in, organisational and managerial support with effective leadership, and a receptive setting (some community nursing and acute wards may not be appropriate).

In total, 102 women were recruited to the patient-reported outcome measures study from across five sites. Baseline questionnaires were available from 91 women. Seventy-one women completed the 6-month follow-up questionnaire, 68 of the baseline questionnaires were matched to 6-month questionnaires, and 72 women with baseline or 6-month questionnaires also had a clinical assessment form completed. Only 59 women had baseline and 6-month questionnaires plus a clinical assessment form.

Research question 2

Research question 2 was analysed using a paired *t*-test of the Pelvic Organ Prolapse Symptom Scores at baseline and at the 6-month follow-up. There were 65 women with both baseline and 6-month Pelvic Organ Prolapse Symptom Scores. The mean Pelvic Organ Prolapse Symptom Score was 10.18 points at baseline and 6.96 points at the 6-month follow-up. Prolapse symptom severity was significantly lower at the 6-month follow-up than at baseline. The difference between baseline and 6 months is 3.2 points on the Pelvic Organ Prolapse Symptom Score (a difference of 2 points represents a clinically meaningful difference). A significant improvement was still observed at 12 months (although numbers were low).

Research question 3

Research question 3 was analysed using an independent-samples *t*-test. The mean change from baseline to the 6-month follow-up in women who were seen by specialist physiotherapists was compared with the change for women seen by other health-care professionals. Improved outcomes for women following receipt of pelvic floor muscle training were achieved regardless of who delivered the intervention. There was no statistically significant difference between the outcomes obtained from delivery by specialist physiotherapists (mean change in Pelvic Organ Prolapse Symptom Score -3.95 points) and the outcomes obtained from delivery by other health-care professionals (mean change in Pelvic Organ Prolapse Symptom Score -2.81 points, $t = 0.89$, $df = 63$; $p = 0.37$).

Additional (secondary) outcomes showed that there was a significant reduction in the number of health-care visits after the start of the intervention (mean of 1.73 appointments at baseline compared with 0.96 appointments at 6 months).

Research question 4

The economic analysis assessed the resource costs of each clinical site's delivery model of pelvic floor muscle training. Pelvic floor muscle training services that were delivered using higher-band physiotherapists only were more costly than such services delivered using other staff mixes. The main differences between sites were the average amount of clinic time for each woman receiving pelvic floor muscle training and differences in the clinical specialisms of who was providing the treatment. Utility, measured using the EuroQol-5 Dimensions, five-level version, improved by 0.019, on average, over 6 months (0.035 for specialist physiotherapists and 0.012 for other clinicians). No statistically significant difference in improvement in health-related quality of life from baseline to 12 months between participants treated by specialist physiotherapists and participants treated by other clinical staff was found [$t(df = 23) = -0.602$; $p = 0.553$, two-tailed]. Small participant numbers prevented assessment of cost-effectiveness.

Research question 5

Research question 5 was analysed using mixed-effects logistic regression on 'any prolapse-related secondary care treatment' during follow-up, with adjustment for baseline prolapse symptom severity, status of surgery, age group and prolapsed stage, and with random effect of centre (missing prolapse symptom severity imputed at median). This analysis showed that the effect of the original pelvic floor muscle training intervention is statistically significant and is associated with a reduction in the odds of any treatment during follow-up, compared with the control group.

Longitudinal follow-up data for the POPPY trial participants indicated a broadly similar demand for outpatient and inpatient resource use between treatment and control groups. There was not an observed difference in estimated resource use between groups at 11 years post pelvic floor muscle training. Resource use cost estimation is limited because 84% of records in the outpatient data set did not have sufficient information about condition or procedure.

The dissemination and implementation workshops were attended by 120 participants (72 in London and 48 in Glasgow) and identified key barriers (and facilitators) in line with those experienced in the realist evaluation. The presentation of the PROPEL intervention findings allowed for discussion of

the possibility of different ways to deliver pelvic floor muscle training. This 'evidence base' helped the majority of participants to shift to thinking 'change' was possible and to begin action plans to take back to their local services.

Conclusions

It is possible to train different staff types/skill mixes to effectively deliver pelvic floor muscle training to women. Women's self-reported outcomes significantly improved across all service models delivering pelvic floor muscle training. The PROlapse and Pelvic floor muscle training: implementing Evidence Locally (PROPEL) intervention has demonstrated how different models and service contexts can affect implementation, but, if these are addressed in advance, then there will be a greater likelihood of successful integration with existing care pathways and greater opportunities for ensuring that (non-specialist) staff delivering pelvic floor muscle training are supported to deliver pelvic floor muscle training with appropriately triaged patients and appropriate clinical supervision. Services delivered using higher-band physiotherapists only were more costly than services delivered using other staff mixes.

The realist evaluation, combined with the robust outcomes data, confirms that pelvic floor muscle training can be successfully delivered using a range of staff/skill mixes and in different NHS settings, and that outcomes are not compromised by different delivery models. This study supports further roll-out of delivery of pelvic floor muscle training (beyond delivery by specialist physiotherapists) by clinicians (nurses, other physiotherapists) who have an interest in women's health.

Implications for practice

The evidence supports training a broader range of health-care professionals with an interest in women's health and/or with a knowledge of physiology/body muscles to deliver pelvic floor muscle training to women.

Delivery of pelvic floor muscle training by other clinicians was supported by specialist physiotherapists undertaking triage of women to determine their suitability for pelvic floor muscle training. The role of the specialist physiotherapist could then be enhanced to provide education and support to other health-care professionals to enable them to safely deliver pelvic floor muscle training to women, while managing more complex cases of pelvic floor prolapse themselves.

Increasing the use of and referral for pelvic floor muscle training as a first-line treatment was facilitated by improved multidisciplinary team working across urogynaecology services and improved communication with primary care. A review of existing pathways to pelvic floor muscle training could identify areas for improvement.

Primary care referrals for pelvic floor muscle training as a first-line treatment for pelvic organ prolapse would probably increase with more awareness-raising (of pelvic organ prolapse and pelvic floor muscle training) and education for general practitioners and other primary health-care professionals.

Study registration

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